

### REMARKS

The present document is submitted in response to the Office Action dated March 24, 2008 ("Office Action").

Applicants have amended claims 1 and 8-10 to promote clarity. More specifically, Applicants have followed the Examiner's suggested claim amendments presented in the Office Action at page 3, section 4; and page 5, section 5 (first paragraph). Further, Applicants have added new claims 26 and 27, support for which appears in the specification at page 5, lines 17-18. Finally, Applicants have cancelled claims 7, 11-20, and 22-25.

Upon entry of the present amendments, claims 1, 8-10, 26, and 27 will be pending and under examination. In view of the following remarks, Applicants respectfully submit that this application is now in condition for allowance.

#### Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 8-10 and 20-25 are rejected as indefinite on various grounds. See the Office Action, pages 3-5, sections 3 and 4. Note that Applicants previously cancelled claim 21 and have now cancelled claims 20 and 22-25. Therefore, Applicants address below only the grounds for rejecting claims 8-10.

The Examiner states that the term "the allele" recited in previously presented claims 8-10 has no antecedent basis. See the Office Action, page 3, 1<sup>st</sup>- 4<sup>th</sup> paragraphs. Applicants have amended claim 1, from which claims 8-10 depend, to add therein the term "an HLA-B\*1502 allele," which provides antecedence for the term at issue.

Next, the Examiner points out that the term "the nucleic acid" recited in claim 8 has no antecedent basis. See the Office Action, page 3, 3<sup>rd</sup> paragraph. Applicants have deleted this term.

Finally, the term "the peripheral blood" recited in claims 9 and 10 is deemed lacking antecedence. See the Office Action, page 3, 4<sup>th</sup> paragraph. Following the Examiner's suggestion, Applicants have removed "the" from this term, thereby rendering the rejection moot.

Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

The Examiner rejects claims 1 and 8-12 for lack of enablement. These claims cover a method for assessing a risk of a human patient for developing an adverse drug reaction based on the presence of HLA-B\*1502. The Examiner is of the position that the rejected claims are overly broad, i.e., encompassing detection of HLA-B\*1502 in **any non-patient sample** or by examining **any equivalent genetic markers**. See the Office Action, pages 5-10; emphases added.

Applicants have amended independent claim 1, following the Examiner's proposed claim amendments. See page 5, 2<sup>nd</sup> paragraph. This claim, as amended, covers a method of assessing the above-mentioned risk by detecting the presence of **HLA-B\*1502, not any equivalent genetic marker, in a sample obtained from a patient**. It is submitted that, as the Examiner correctly points out (see page 5, 2<sup>nd</sup> paragraph), amended claim 1 meets the enablement requirement. Claims 8-10, all dependent from claim 1, are rejected on the same ground. The amendment to claim 1 therefore has also overcome the rejection of these claims. Claims 11 and 12, the other two rejected claims, have been cancelled.

Applicants respectfully request that the Examiner withdraw this rejection.

Rejection under 35 U.S.C. § 102

Claims 20, 23, and 25 stand rejected for anticipation by Trachtenberg, US Patent 5,550,039 ("Trachtenberg"). Applicants have cancelled these claims.

Rejection under 35 U.S.C. § 103

Claims 22 and 24 are rejected as obvious over Trachtenberg in view of Yates et al. These two claims have been cancelled.

New Claims

Applicants have added new claims 26 and 27, both of which depend from claim 1. These two claims, in combination, cover the same subject matter as amended claim 1.

As claim 1 is not rejected for anticipation or obviousness based on Trachtenberg and Yates et al., Applicants submit that claims 26 and 27, dependent from claim 1, are novel and non-obvious in view of these two cited references.

Applicants would also like to point out that new claims 26 and 27 recite the same language as amended claim 1. As the Examiner does not reject claim 1 for infiniteness, the two new claims are clearly definite.

Finally, for the reasons set forth at page 5 supra, claim 1, as amended, satisfies the enablement requirement. New claims 26 and 27 have the same claim scope as amended claim 1, since these two claims, in combination, cover the same subject matter as claim 1. They therefore also meet the enablement requirement.

#### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment.

In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.


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No fee is believed to be due. Please apply any charges to Deposit Account No.  
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Respectfully submitted,

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